EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

FEB 14 2006

The Honorable Henry Waxman
U.S. House of Representatives
Washington, D.C. 20515

Dear Henry,

Thank you for your letter regarding aspects of the intellectual property chapter of the U.S. – Andean Trade Promotion Agreement (USA-TPA).

The free trade agreements (FTAs) negotiated by USTR are consistent with U.S. law and do not adversely affect access to medicines. Consistent with the Trade Promotion Authority objectives established by Congress, USTR seeks intellectual property rights provisions that reflect a standard of protection similar to that found in United States law, which promotes a balance between innovation and access for pharmaceutical products. All of the intellectual property rights provisions, including provisions related to pharmaceutical patents and data protection, are consistent with and do not go beyond U.S. law, thus preserving the approach we have here in the United States and ensuring that our trading partners can strike the same balance.

In negotiating the intellectual property provisions in our FTAs, we strive for provisions that both ensure adequate protection of intellectual property and allow the flexibility to implement the obligations under the different legal systems of our trading partners. Our FTA provisions successfully strike that balance.

Additionally, we believe that the intellectual property provisions in our FTAs can advance our partners' ability to address public health problems by providing incentives for the development of new medicines and by raising the standards of living more broadly, while promoting access to affordable generic medicines.

In your letter, you expressed concerns with the possible inclusion of a number of specific provisions in the USA-TPA. As you are aware, we have recently closed negotiations for the U.S. – Peru Trade Promotion Agreement (PTPA). With respect to the PTPA, I would note that:

- the IP chapter does not require patents to be granted for diagnostic, therapeutic or surgical methods for the treatment of humans and animals;
- the obligation to provide "at least" 5 years of data protection is consistent with U.S. law and in no way obligates the United States or Peru to consider providing data protection for a longer term;
- there is no obligation in the IP chapter to grant patents to new uses of patented products;

- there is no obligation for national drug authorities to "enforce" drug; and
- there is no restriction on the ability of a country to allow parallel imports of drugs.

You also specified three provisions that you believe would promote greater access to medicines, if included. With respect to those three issues, we note that the PTPA:

- does contain a "Bolar"-type provision, consistent with U.S. law, to permit a country to implement this exception;
- does not contain an obligation to disclose "best mode" but does specifically permit the Parties to require such a disclosure; and
- does not provide specific caps or floors on patent term adjustments made to compensate patent owners for delays in granting a patent or a marketing approval. The PTPA permits Peru to implement a system of patent term adjustment that is most appropriate for Peru, taking into consideration the factors it believes to be important, including the workings of its own patent system and the marketing approval process.

Thank you for your correspondence, and I look forward to working with you.

Sincerely,

Rob Portman